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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,282	08/24/2000	Brent R. Constantz	CORA-011	5591

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
3763	1

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

CC

Office Action Summary	Application No.	Applicant(s)
	09/648,282	CONSTANTZ ET AL.
Examiner	Art Unit	
Roz Ghafoorian	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 March 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6-7, 9, 11-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6, 7, 9 and 11-50 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Specification

1. The amendment filed 3-17-2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the applicant has amended the claims to read on a "vascular lesion", and has directed the examiner to page 5 line 13 of the specification however there is no mention of "vascular lesion" fluid in page 5 or any where in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-4,6-7,9,11-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant has amended the claims to read on a "vascular lesion", and has directed the examiner to

page 5 line 13 of the specification however there is no mention of "vascular lesion" fluid in page 5 or any where in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in–
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 1-4, 6-7, 9, 15-19, 21-29, 31-36, 42-45, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No.6290689 to Delaney et al.

Delaney teaches a system with a multi-lumen catheter, a fluid delivery system with two fluid reservoirs comprising of dissolution and a dissolution fluid attenuating fluid and negative pressure means sufficient to aspirate. The fluid system comprises of a first and second reservoir, as well as a balloon inflation system and a third lumen in the catheter. The dissolution fluid is a buffer, which is a pH elevating solution as, and organic matter dissolution is detergent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 46, 21 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6471674 to Emig.

Emig teaches a fluid storage means comprising first and second fluid reservoirs. Emig Does not teach a vascular lesion dissolution fluid. However, it would have been obvious to one having ordinary skill in the art to have modified the fluid with in the reservoir to allow the physician to use the same device for a different surgical procedure.

5. Claims 1-4,6-7,9, 12-19, 42-45, 47, 50 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6471674 to Emig and further in view of US Patent No.5792157 to Mische.

Emig teaches fluid delivery system 100 with negative pressure means 230, two separate fluid dispensing means 500 and 300, the dispensing means comprises means 320 and 520 for increasing internal pressure of each of the first and second reservoirs.

Emig teaches the invention except for a multi-lumen catheter with a balloon. Emig does discuss a catheter however; it does not describe the details structure of the catheter used. Mische teaches a multi-lumen catheter with a balloon for aspiration and irrigation purpose.

Therefore it would have been an obvious to one having ordinary skill in the art at the time the invention was made to have added a multi-lumen catheter with a balloon to Emig's system, because according to Mische this catheter allows for expansion of the lumen to allow the removal of debris. And since Emig's system is for both irrigation and aspiration it would be obvious to have a catheter with multi-lumens to allow for both aspiration and irrigation.

6. Claims 11, 20, 22, 30-41, 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No.6471674 to Emig, in view of US Patent No.5792157 to Mische and further in view of US Patent No.6033392 to Frey et al.

As mentioned above Emig teaches the invention except for a multi-lumen catheter with a balloon and cartridge. Emig does discuss a catheter however; it does not describe the details structure of the catheter used. Mische teaches a multi-lumen catheter with a balloon for aspiration and irrigation purpose. Frey teaches a cartridge for placement of fluid reservoirs.

Therefore it would have been an obvious to one having ordinary skill in the art at the time the invention was made to have added a multi-lumen catheter with a balloon to Emig's system as well as a cartridge because according to Frey adding a cartridge will allow the fluid reservoirs to be in an antibacterial environment.

Response to Arguments

7. Applicant's arguments filed 3-17-2003 have been fully considered but they are not persuasive.

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a. The applicant alleges Delaney does not teach a metered fluid. Since the applicant has failed to define the word "metered" the examiner has taken the dictionary meaning of metered which means to measure, hence the claimed requires some kind of measurement of the fluid, which is being, used form the reservoir and Delaney's syringe reservoir contains measuring lines which allows the gave giver to "measure" the amount of fluid leaving the syringe. Hence Delaney does teach a means of metering fluid.

a. Applicant's arguments with respect to claims 21-46 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
May 16, 2003

Michael J. Hayes
MICHAEL J. HAYES
PRIMARY EXAMINER